Remarks

Claims 1-20 are pending in the application. The claims are rejected as anticipated and as obvious.

Rejection under 35 USC 102(b)

Claims 1 and 2 are rejected as anticipated by Meryman et al., WO91/04659 ("Meryman"). The rejection is traversed.

Claim 1, from which depends claim 2, is drawn to a method that requires providing a starting blood cell suspension in a volume greater than 50 mL. Meryman does not describe a method with this feature. Meryman therefore does not anticipate the invention of claims 1 and 2.

Applicants request reconsideration and withdrawal of the rejection for anticipation.

Rejection under 35 USC 103(a)

Claims 1-5 and 13-20 are rejected as unpatentable over Maryman and Edson et al., WO00/18969 ("Edson"). The rejection is traversed.

Claim 1, from which depend the remaining claims subject to the rejection, is drawn to a method for reducing the concentration of an analyte in a blood cell suspension. The claimed method requires, *inter alia*, providing a starting blood cell suspension in a volume greater than 50 mL (step (i)) and washing the starting blood cell suspension with a wash solution under conditions sufficient to lower the concentration of the analyte at least 10^3-fold relative to the analyte concentration in the starting blood cell suspension (step (ii)). The claim further requires that the blood cells of the blood cell suspension retain viability after a storage period of greater than 21 days at 4 °C in a storage solution (step (ii)).

In order to establish a case of obviousness by combining references there must be a suggestion or motivation for such a combination originating within the references themselves. The resulting combination must arrive at the claimed invention considered as a whole. The Federal Circuit has stated (In re Vaeck, 20 USPQ2d 1438, 1442, 1991):

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this [invention] should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

Meryman describes methods for prolonging the shelf life of transfusible red blood cells by decreasing the effective osmolality of a suspending solution, and by increasing the intracellular pH of cells prior to storage. However, it does not teach suggestions in which analytes can be removed from a large initial volume of blood cells under conditions that allow the blood cells to retain viability after long term storage. In addition, Meryman notes the difficulties in storing blood, and in using blood products that have been treated to inactivate viruses (see pages 1-5 of Meryman). There is no suggestion in this reference of Applicants' claimed method.

Edson, which is cited for describing methods for separating red blood cells from other blood components and from ethyleinimine oligomer inactivating agents, does not overcome the deficiencies of Meryman. Moreover, there is no suggestion in either Meryman or Edson of a method that takes a starting cell volume greater than 50 ml and then washes the cells under conditions that effect a 10^3-fold reduction in an analyte concentration, and which also allow the blood cell suspension to retain viability after a storage period of greater than 21 days at 4 °C . Nor is there any suggestion from the combination of references that the method would be successful.

In view of the foregoing comments, Applicants request reconsideration and withdrawal of the rejection for obviousness.

A petition for extension of time accompanies this response. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, (Reference No. 18242-508 CIP2). A duplicate copy of this Petition is enclosed.

Respectfully submitted,

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